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VIA ECF

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Re: Calchi v. GlaxoSmithKline Consumer Healthcare Holdings (US) LLC et al., No. 7:22-cv-01341 (S.D.N.Y.)

Dear Counsel:

We represent Defendants GlaxoSmithKline Consumer Healthcare Holdings (US) LLC, GSK Consumer Health, Inc., and Pfizer Inc. (collectively, "Defendants") in this matter.[1] Pursuant to the Court's Individual Rules of Practice, we provide this pre-motion letter regarding Defendants' anticipated motion to dismiss Plaintiff Nancy Calchi's Complaint.

Plaintiff allegedly purchased Robitussin Cough + Chest Congestion DM in 2021, though she does not allege specific facts about the transaction, including when in 2021 she purchased it, where she purchased it, or how much she paid. Compl. ¶ 34. According to Plaintiff, she purchased the Robitussin product because it was labeled "non-drowsy," and claims she became drowsy at some point after ingesting the product. *Id.* Plaintiff now brings this action alleging that a variety of

[1] Pfizer is not a proper defendant in this action. On December 19, 2018, GSK entered into a Stock and Asset Purchase Agreement ("SAPA") with Pfizer, pursuant to which GSK agreed to acquire Pfizer's consumer healthcare business. *See* SAPA, Ex. 4.10 to GSK 2018 Form 20-F. Under the SAPA, GSK acquired rights related to certain products, including Pfizer's Robitussin product, and assumed all liabilities of Pfizer's consumer healthcare business regardless of whether they arose prior to, on, or after the close of the transaction. *See id.*, at Section 2.4.

Robitussin products (the "Non-Drowsy Products") are misleadingly labeled as "non-drowsy" because one of the active ingredients in the products—dextromethorphan hydrobromide ("DXM")—allegedly can cause drowsiness. *Id.* ¶¶ 1-2. Based on these allegations, Plaintiff brings the following claims: (i) violations of the state consumer protection acts of 43 states and the District of Columbia; (ii) violation of New York Gen. Bus. Law § 349; (iii) violation of New York Gen. Bus. Law § 350; (iv) breach of express warranty; (v) breach of the Magnuson-Moss Warranty Act ("MMWA"); and (vi) intentional misrepresentation.

Plaintiff's claims should be dismissed for at least the following reasons: (1) her claims are preempted by federal law; (2) Plaintiff fails to allege facts demonstrating that "non-drowsy" is a false or misleading description of the products; (3) Plaintiff's N.Y. Gen. Bus. Law (GBL), express warranty, and MMWA claims suffer from additional deficiencies; (4) Plaintiff lacks standing to seek injunctive relief; and (5) Plaintiff lacks standing for causes of action based on the laws of states other than New York.

I. Plaintiff's Claims are Preempted.

The Food, Drug, and Cosmetic Act ("FDCA") expressly preempts state law claims like Plaintiff's seeking to impose requirements that are "different from," "in addition to," or "otherwise not identical with" federal labeling requirements concerning over-the-counter ("OTC") drugs. 21 U.S.C. § 379r(a). Preemption under the FDCA applies both "when a state law prohibits labeling that is permitted under federal law" and "when a state law prohibits labeling that is ***not prohibited*** under federal law." *Bowling v. Johnson & Johnson*, 65 F. Supp. 3d 371, 375 (S.D.N.Y. 2014) (italics in original). State law that "diverges from federal law at all" is preempted. *Id.*; *see also Critcher v. L'Oreal USA, Inc.*, 959 F.3d 31, 35-36 (2d Cir. 2020) (finding analogous provision preempts "***any*** state law that provides for labeling requirements that are not ***exactly the same*** as those set forth in the FDCA and its regulations") (italics in original).

The U.S. Food & Drug Administration ("FDA") has issued a monograph identifying specific indications, warnings, and directions that must appear on labels of OTC medications containing DXM, like the Non-Drowsy Products. *See* 21 C.F.R. § 341.74. An OTC antitussive product is not misbranded if it complies with the monograph requirements (and other general formatting requirements). 21 C.F.R. § 341.1(a).

Plaintiff alleges that the Non-Drowsy Products "do not disclose anywhere on their packaging that they do or can cause drowsiness, or that drowsiness is a side effect." Compl. ¶ 17. In other words, Plaintiff is demanding that Defendants include a drowsiness warning. But the FDA has considered and ***expressly declined*** as part of the monograph to require a "drowsiness" warning as a possible DXM side effect. *See* 21 C.F.R. § 341.74; *see also* 48 Fed. Reg. 48,576, 48,589 (Oct. 19, 1983) ("The agency is not aware of data demonstrating that the antitussive ingredients codeine and dextromethorphan could be classified as Category I nighttime sleep-aids ***or that they require a drowsiness warning***.") (emphasis added). In light of that determination, it is unsurprising that the monograph does not prohibit labeling a DXM product as "non-drowsy." The absence of any

"drowsy" warning requirement for DXM products supports a "non-drowsy" label to differentiate them from other cough and cold products that must carry a "drowsy" warning under the monograph.[2] Simply put, if a product is considered by the FDA to not cause drowsiness, by definition it is non-drowsy.

Permitting Plaintiff to proceed with her claims "would be using state law to impose labeling requirements on top of those already mandated in the FDCA and the regulations promulgated thereunder," which "is exactly what the FDCA does not permit." *Crichter*, 959 F.3d at 36; *see also Bowling*, 65 F. Supp. 3d at 375 (state law claims are preempted "unless they are ***identical*** to federal standards" set forth in an FDA monograph) (italics in original). Her claims thus are preempted by § 379r(a). Plaintiff's claims also are impliedly preempted under principles of conflict and field preemption because varying state labeling requirements for active ingredients would interfere with the FDA's regulatory scheme for antitussive products and the FDA's exclusive and extensive regulation in this field has been sufficiently comprehensive, leaving no room for state supplementation.

II. Plaintiff Fails to Plausibly Allege That "Non-Drowsy" is False or Misleading.

There are additional grounds that independently support dismissal. Plaintiff's warranty and GBL claims require a misleading, false, or inaccurate statement. *See Lugones v. Pete & Gerry's Organic, LLC*, 440 F. Supp. 3d 226, 244 (S.D.N.Y. 2020) (warranty claims require "a material statement amounting to a warranty" and "breach of this warranty") (emphasis omitted); *Chen v. Dunkin' Brands, Inc*., 954 F.3d 492, 500 (2d Cir. 2020) (GBL § 349 claim requires a "deceptive act[]"); *Goshen v. Mut. Life Ins. Co. of N.Y*., 98 N.Y.2d 314, 324 n.1 (2002) ("The standard for recovery under [GBL] § 350, while specific to false advertising, is otherwise identical to section 349."). Misleading or false statements are ones to "likely to mislead a reasonable consumer acting reasonably under the circumstances." *Oswego Laborers' Local 214 Pension Fund v. Marine Midland Bank*, 85 N.Y.2d 20, 26 (N.Y. 1995); *see also Hesse v. Godiva Chocolatier, Inc*., 463 F. Supp. 3d 453, 469 (S.D.N.Y. 2020) (warranty claim requires a misrepresentation "material to a reasonable consumer") (citation omitted). Courts may determine that an alleged deceptive advertisement would not mislead reasonable consumers as a matter of law. *Fink v. Time Warner Cable*, 714 F.3d 739, 741 (2d Cir. 2013).

Although Plaintiff's allegations center on her claim that ***the ingredient*** DXM ***in isolation*** causes drowsiness, she fails to sufficiently allege that the ***Robitussin product as a whole*** causes drowsiness. To the contrary, the Complaint's purported sources for such a claim, even as to the DXM ingredient alone, do not support Plaintiff's contention that DXM causes drowsiness.

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[2] For instance, antitussive products containing diphenhydramine must warn that they "may cause marked drowsiness." 21 C.F.R. § 341.74(c)(4)(ix).

A. Plaintiff's allegations do not address the Non-Drowsy Products and therefore are defective.

Plaintiff's claims focus on DXM in isolation. But Plaintiff did not ingest DXM in isolation, she ingested a product (Robitussin Cough + Chest Congestion DM) composed of active and inactive ingredients in addition to DXM. Compl. ¶ 34. Because Plaintiff does not allege that the Robitussin Cough + Chest Congestion DM product with this combination of ingredients causes drowsiness, the Complaint should be dismissed. *See In re GNC Corp.*, 789 F.3d 505, 516-17 (4th Cir. 2015) (affirming dismissal of claim that certain ingredients rendered supplement ineffective where plaintiffs failed to plausibly allege falsity of representations regarding the products as a whole); *Eckler v. Wal-Mart Stores, Inc.*, No. 12-CV-727-LAB-MDD, 2012 WL 5382218, at *6 (S.D. Cal. Nov. 1, 2012) (dismissing false advertising claim where "none of these studies actually involved" the product at issue and "it is that overall formulation that's behind the representation at issue"); *Toback v. GNC Holdings, Inc.*, No. 13-80526-CIV, 2013 WL 5206103, at *5 (S.D. Fla. 2013) (finding allegations concerning the inefficacy of two ingredients did not plausibly suggest that the product "as a whole does not function as advertised").

B. Plaintiff does not plausibly allege that DXM causes drowsiness.

Plaintiff fails to plead facts plausibly showing that "non-drowsy" is misleading to a reasonable consumer, even considering DXM isolation, and the sources cited in the Complaint refute her allegations. For example, she relies on a 1997 study to support her claim that drowsiness is a common side effect at recommended dosages of DXM. Compl. ¶ 21. This study, among other things, observed that drowsiness is a ***rare side effect***, noting that "***somnolence was reported for a low percentage of patients***" taking DXM. E. Catena and L. Daffonchio, "Efficacy and Tolerability of Levodropropizine in Adult Patients with Non-productive Cough. Comparison with Dextromethorphan," 10 Pulmonary Pharmacology & Therapeutics 89, 89 (1997) (emphasis added). The relevant issue here is not whether the product causes drowsiness for a low percentage of consumers but rather whether "non-drowsy" is misleading to "a significant portion of the general consuming public or of targeted customers." *Jessani v. Monini N. Am., Inc.*, 744 F. App'x 18, 19 (2d Cir. 2018).

Plaintiff also alleges that "[t]he FDA's adverse event report database confirms that 'sedation' is one of the most frequently-cited side-effects of [DXM]-containing products." Compl. ¶ 22. But the FDA cautions that reports in the FDA adverse reports database do not establish causation. They are duplicative, unverified, incomplete, and "do[] not mean that the drug or biologic caused the adverse event."[3] They, therefore, do not plausibly support a causation allegation. *See Twohig v. Shop-Rite Supermarkets, Inc.*, 519 F. Supp. 3d 154, 163 (S.D.N.Y. 2021) (plaintiff's study did not support GBL claims as it was "sufficiently flawed that it [did] not contribute enough to render

[3] https://www.fda.gov/drugs/questions-and-answers-fdas-adverse-event-reporting-system-faers/fda-adverse-event-reporting-system-faers-public-dashboard (last visited Mar. 25, 2022).

the claims plausible"); *see Mizel Roth IRA on Behalf of Consol. Asset Funding 3 LP v. Unified Capital Partners 3 LLC*, No. 19 Civ. 10712, 2021 WL 1164439, at *1 (S.D.N.Y. Mar. 25, 2021) ("court need not accept the allegations in the complaint as true" where the materials cited "in the complaint contradict[] allegations in the complaint").

Similarly, the FAA's alleged prohibition of pilots ingesting DXM before flying is unhelpful to Plaintiff. Compl. ¶ 23. The FAA guidance focuses on "combination products ***with sedating antihistamines***," and even acknowledges that "[m]ost cough medications are safe for flight." *Id.* (emphasis added). Robitussin does not contain an antihistamine. *See* 21 C.F.R. § 341.12 (identifying antihistamine ingredients). In any event, the FAA's guidance to pilots has no bearing on whether the statement "non-drowsy" is misleading to "a significant portion of the general consuming public or of targeted customers." *Jessani*, 744 F. App'x at 19.

III. Plaintiff's GBL and Express Warranty Claims Fail on Independent Grounds.

In addition to being preempted and subject to dismissal for failure to allege a misleading or false statement, Plaintiff's GBL and express warranty claims fail for several independent reasons. Plaintiff's GBL claims are barred by the GBL's "safe harbor" clauses providing a "complete defense" to claims challenging advertising or conduct that is "subject to and complies with the rules and regulations" of any federal agency, including the FDA. N.Y. Gen. Bus. L. §§ 349(d), 350-d; *see also Am. Home Prods. Corp. v. Johnson & Johnson*, 672 F. Supp. 135, 144 (S.D.N.Y. 1987) (holding that compliance with FDA regulations governing over-the-counter warning requirements was "complete defense").

Moreover, Plaintiff's conclusory allegations that she would not have purchased Robitussin and/or that she paid a "price premium" for it do not satisfy the "actual injury" element requirements. Compl. ¶¶ 33, 34, 59. It is "well-settled" that under the GBL, a consumer "whose purchase was allegedly procured through deception" is unable to recover "a refund of the price." *Dash v. Seagate Tech. (U.S.) Holdings, Inc.*, 27 F. Supp. 3d 357, 361 (E.D.N.Y. 2014). Moreover, Plaintiff does not allege that she considered any less expensive comparable DXM product that did not include a "non-drowsy" label. Plaintiff's conclusory assertions of a "price premium" do not plausibly state a claim. *Izquierdo v. Mondelez Int'l, Inc.*, No. 16-cv-04697 (CM), 2016 WL 6459832, at *7 (S.D.N.Y. Oct. 26, 2016); *see also Colella v. Atkins Nutritionals, Inc.*, 348 F. Supp. 3d 120, 143 (E.D.N.Y. 2018) (finding that the plaintiff failed to state a GBL claim where he provided "no facts regarding what the premium was, what price he paid for the products, or the price of non-premium products").

Plaintiff's express warranty claim is similarly deficient due to Plaintiff's failure to allege that she paid any price premium, *see Bennett v. U.S. Trust Co.*, 770 F.2d 308, 316 (2d Cir. 1985) ("[u]nder New York law, breach of warranty damages are usually measured by the benefit of the bargain rule"), and for the additional reason that Plaintiff does not allege specific facts to demonstrate that she notified Defendants of the alleged breach within a reasonable time after its discovery, *see Mid Island LP v. Hess Corp.*, 983 N.Y.S.2d 204, 2013 WL 6421281, at *4 (Sup. Ct. N.Y. Cnty. Dec. 2,

2013) (dismissing warranty claim where the complaint was "silent as to when the plaintiffs discovered the supposed breach").

IV. Plaintiff's MMWA Claim Fails on Independent Grounds.

Plaintiff's MMWA claim additionally fails for three reasons. *First*, the phrase "non-drowsy" is not a warranty pursuant to the MMWA, but rather a product description. *See Bowling*, 65 F. Supp. 3d at 378 (dismissing MMWA claim because representation "Restores Enamel" on label was merely a product description). *Second*, the MMWA is inapplicable to warranties permitted by the FDCA. 15 U.S.C. § 2311(d) (MMWA is "inapplicable to any written warranty the making or content of which is otherwise governed by Federal law"); *see Hernandez v. Johnson & Johnson Consumer Inc*., No. 3:19-cv-15679-BRM-TJB, 2020 WL 2537633, at *5 (D.N.J. May 19, 2020) (dismissing at pleading stage MMWA claim challenging drug label because the FDCA comprehensively regulates labels for OTC drugs). *Third*, Plaintiff failed to satisfy the $25 amount-in-controversy required for MMWA claims. 15 U.S.C. § 2310(d)(3)(A); *see Ebin v. Kangadis Food Inc.*, No. 13 Civ. 2311, 2013 WL 3936193 (S.D.N.Y. July 26, 2013) (dismissing putative consumer class action MMWA claim at pleading stage for failure to meet jurisdictional prerequisites).

V. Plaintiff Lacks Standing to Seek Injunctive Relief.

Plaintiff seeks injunctive relief as a remedy on the grounds that she "faces an imminent threat of harm because she will not be able to rely on the labels in the future, and thus will not be able to purchase the products." Compl. ¶ 35. Plaintiff has not plausibly alleged a likelihood of future harm because she believes that DXM causes drowsiness and thus will not reasonably be misled by a "non-drowsy" claim on a Robitussin product with DXM as an ingredient. *See, e.g.*, *Berni v. Barilla S.p.A*., 964 F.3d 141, 147 (2d Cir. 2020); *Klausner v. Annie's, Inc*., No. 20-CV-08467, 2022 WL 204356, at *3-4 (S.D.N.Y. Jan. 24, 2022); *Valcarcel v. Ahold U.S.A., Inc*., No. 21-cv-07821, 2021 WL 6106209, at *10 (S.D.N.Y. Dec. 22, 2021). Further, injunctive relief is not available where, as here, there is an adequate remedy at law. *Berni*, 964 F.3d at 146-47 ("[I]njunctive relief is only proper when a plaintiff, lacking an adequate remedy at law, is likely to suffer from injury at the hands of the defendant if the court does not act in equity.").

VI. Plaintiff Cannot Assert Claims Under the Consumer Protection Laws of States Other Than New York.

Finally, Plaintiff does not have standing to pursue for herself claims under the consumer protection laws of any state other than New York. *Jurgensen v. Felix Storch, Inc*., No. 12 Civ. 1201, 2012 WL 2354247, at *10 (S.D.N.Y. June 14, 2012) (finding plaintiff "does not have standing to bring claims for violations of consumer fraud statutes of states other than . . . the state where she

resides").[4] Moreover, the Complaint merely identifies a host of statutes allegedly violated without any supporting factual allegations, a practice rejected by the Second Circuit. *See In re Aluminum Warehousing Antitrust Litig*., 833 F.3d 151, 163 (2d Cir. 2016) (holding that state consumer protection claims should be dismissed when "[t]he complaint does little more than list a couple dozen state statutes in alphabetical order by state, without pleading any of their elements").

* * *

For the foregoing reasons, Defendants intend to move to dismiss the Complaint should Plaintiff choose not to amend.

Sincerely,
Grant R. MacQueen

Grant R. MacQueen
J. Gordon Cooney, Jr. (motion for admission *pro hac vice* forthcoming)

cc: Hon. Kenneth M. Karas and all counsel (via ECF)

[4] Even if Plaintiff did have standing (and she does not), she failed to comply with certain pre-filing notice requirements. For example, Massachusetts law requires that a written demand for relief be served thirty days before the filing of a complaint, whereas she provided only five. *Corbett v. PharmaCare U.S., Inc*., No. 21-cv-137, 2021 WL 4866124 (S.D. Cal. Oct. 19, 2021) (dismissing M.G.L. ch. 93A claim for failure to comply with thirty-day requirement).